# General

## Guideline Title

Guidance on prevention of viral hepatitis B and C among people who inject drugs.

## Bibliographic Source(s)

World Health Organization. Guidance on prevention of viral hepatitis B and C among people who inject drugs. Geneva (Switzerland): World Health Organization (WHO); 2012. 46 p. [142 references]

## Guideline Status

This is the current release of the guideline.

# Regulatory Alert

## FDA Warning/Regulatory Alert

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- March 22, 2016 – Opioid pain medicines : The U.S. Food and Drug Administration (FDA) is warning about several safety issues with the entire class of opioid pain medicines. These safety risks are potentially harmful interactions with numerous other medications, problems with the adrenal glands, and decreased sex hormone levels. They are requiring changes to the labels of all opioid drugs to warn about these risks.

# Recommendations

## Major Recommendations

Ratings schemes for the level of evidence (*high, moderate, low, very low*) and the strength of the recommendations (*strong, conditional*) are defined at the end of the "Major Recommendations" field.

Hepatitis B Vaccination

Recommendation 1: It is suggested to offer people who inject drugs the rapid hepatitis B vaccination regimen. *Conditional recommendation, very low-quality evidence*

*Complementary Remarks*

- A higher-dose hepatitis B virus (HBV) vaccine should be used with the rapid regimen.
- HBV vaccine is already strongly recommended for people who inject drugs (PWID), per World Health Organization (WHO) guidelines.
- The priority for any regimen is delivery of the first dose of vaccine.
- Completion of three doses is more important than following a specific schedule. A missed dose should be given at the earliest opportunity without re-initiating the regimen.
- Individuals with inadequately treated human immunodeficiency virus (HIV) or with chronic hepatitis C virus (HCV) may have suppressed immunogenicity and may benefit more from the standard regimen.
- Both rapid and standard HBV vaccine regimens should be offered to PWID.

Recommendation 2: It is suggested to offer people who inject drugs incentives to increase uptake and completion of the hepatitis B vaccine schedule. *Conditional recommendation, very low- to low-quality evidence*

*Complementary Remarks*

- Vaccinations should be provided at a location and time convenient for PWID.
- This recommendation applies to settings with lower vaccination uptake rates among PWID and where other efforts to increase vaccination uptake are already in place.
- This recommendation is conditioned on local acceptability and resource availability.
- An inability to provide incentives should not discourage countries or settings from offering HBV vaccination to PWID.

Type of Syringes

Recommendation 3: It is suggested that needle and syringe programs also provide low dead-space syringes for distribution to people who inject drugs. *Conditional recommendation, very low-quality evidence*

*Complementary Remarks*

- Needle and syringe programmes should offer all types of syringes appropriate for local needs.
- Low dead-space syringes (LDSS) are currently produced in a limited number of sizes. Larger syringes should also be offered if appropriate to local needs, regardless of dead-space volume.
- Education should be provided to PWID and programme planners on the advantages of LDSS.
- Needle and syringe programmes (NSPs) should also provide other injecting paraphernalia, such as cotton, spoons, etc.
- LDSS syringes should also be available at other sites for syringe distribution i.e., pharmacies.

Psychosocial and Peer Interventions

Recommendation 4: Psychosocial interventions are not suggested for people who inject drugs to reduce the incidence of viral hepatitis. *Conditional recommendation, very low- to low-quality evidence*

*Complementary Remarks*

- Psychosocial interventions should not be suggested as a stand-alone intervention for the prevention of viral hepatitis.
- Psychosocial interventions should not be excluded as part of comprehensive intervention for drug dependence treatment or other outcomes.
- This recommendation does not include peer-delivered interventions.
- PWID should always be offered access to needle and syringe programmes.
- PWID should always be offered access to effective substance use treatment programmes, in particular opioid substitution therapy for those dependent on opioids.

Recommendation 5: It is suggested to offer peer interventions to people who inject drugs to reduce the incidence of viral hepatitis. *Conditional recommendation, low- to moderate-quality evidence*

*Complementary Remarks*

- Involving peers is an important modality of service delivery to PWID, as described in the WHO Evidence for Action Series: Technical papers and policy briefs on HIV/AIDS and injecting drug users.

Definitions:

Grading of Recommendations Assessment, Development and Evaluation (GRADE) Notation and Language

| Grade Methodology Notation | Interpretation | Language Used in the Guidelines |
|---|---|---|
| Strong recommendation for | The panel concluded that the availability and quality of relevant scientific evidence, together with data on cost and feasibility issues, and community preferences and values, were enough to categorically support the intervention under review. | An intervention is recommended (or The panel recommends…). |
| Strong recommendation against | The panel concluded that the availability and quality of relevant scientific evidence, together with data on cost and feasibility issues, and community preferences and values, were enough to categorically recommend against the intervention under review. | An intervention is not recommended (or The panel recommends against…). |
| Conditional recommendation for | The panel concluded that the availability and quality of relevant scientific evidence, together with data on cost and feasibility issues, and community preferences and values, were not enough to categorically support the intervention under review. However, benefits may outweigh costs/risks, and this intervention should be considered in light of locally relevant needs, resources and priorities. | An intervention is suggested (or The panel suggests…). |
| Conditional recommendation against | The panel concluded that the availability and quality of relevant scientific evidence, together with data on cost and feasibility issues, and community preferences and values, were not enough to categorically recommend against the intervention under review. However, costs/risks may outweigh benefits, and the decision on whether or not to implement it should be made in light of locally relevant needs, resources and priorities, particularly if better interventions are not available. | An intervention is not suggested (or The panel suggests against…). |

Levels of Assessment of the Evidence

| Grade | Definition |
|---|---|
| High | Further research is very unlikely to change confidence in the estimate of effect |
| Moderate | Further research is likely to have an important impact on confidence in the effect |
| Low | Further research is very likely to have an estimate of effect and is likely to change the estimate |
| Very low | Any estimate of effect is very uncertain |

## Clinical Algorithm(s)

None provided

# Scope

## Disease/Condition(s)

- Viral hepatitis B
- Viral hepatitis C

## Guideline Category

Counseling

Management

Prevention

## Clinical Specialty

Family Practice

Infectious Diseases

Internal Medicine

Preventive Medicine

Psychology

## Intended Users

Advanced Practice Nurses

Allied Health Personnel

Emergency Medical Technicians/Paramedics

Health Care Providers

Nurses

Physicians

Psychologists/Non-physician Behavioral Health Clinicians

Public Health Departments

Social Workers

Substance Use Disorders Treatment Providers

## Guideline Objective(s)

- To recommend public health interventions to prevent viral hepatitis B and C among people who inject drugs (PWID)
- To raise awareness on how to prevent hepatitis B virus (HBV) and hepatitis C virus (HCV) infection among PWID
- To provide a tool for policy-making and advocacy as well as clinical guidance for front-line health professionals
- To provide countries and programs with evidence-based recommendations to accomplish the following objectives:
    - Underline the importance of the comprehensive package for human immunodeficiency virus (HIV) prevention, treatment and care for PWID and its relevance for preventing viral hepatitis transmission, in particular with needle and syringe programs and opioid substitution therapy
    - Increase uptake and completion of hepatitis B vaccination among PWID
    - Provide information on potential advantages to and encourage the provision of low dead-space syringes within broader needle syringe programs for PWID
    - Provide clarity concerning the limited effectiveness of psychosocial interventions as a solitary intervention in preventing hepatitis transmission
    - Support peer-based initiatives in programs working with PWID

## Target Population

People who inject drugs who are at risk for viral hepatitis B and C infection

## Interventions and Practices Considered

1. Hepatitis B virus (HBV) vaccination (standard and rapid regimens)
2. Offering incentives for HBV vaccination
3. Providing low dead-space syringes for distribution to people who inject drugs
4. Psychosocial interventions for prevention of hepatitis (not recommended as a stand-alone intervention)
5. Peer interventions for prevention of hepatitis

## Major Outcomes Considered

- Completion of vaccine regimen
- Hepatitis B virus (HBV) vaccine morbidity and mortality
- HBV, hepatitis C virus (HCV), and human immunodeficiency virus (HIV) associated morbidity and mortality
- Satisfaction
- Incidence of HBV, HCV, and HIV infection
- Needle-sharing behavior
- High risk sexual behavior
- Quality of life

# Methodology

## Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Searches of Electronic Databases

## Description of Methods Used to Collect/Select the Evidence

Search Strategies

*General Procedures (Applicable to All Population, Intervention, Comparison and Outcomes [PICO] Questions)*

The researchers searched the following electronic databases; the date ranges used varied by question: PubMed, PsycINFO, Sociological Abstracts, the Cochrane Central Database of Systematic Reviews, CINAHL (Cumulative Index to Nursing and Allied Health Literature), and EMBASE.

For the serosorting question, hand searching in the following journals was also conducted for years 1990-2009: AIDS, JAIDS, AIDS and Behaviour, AIDS Education and Prevention, and AIDS Care.

For the sex venue, internet-based, and social marketing interventions the following databases were also used: LILACS (Latin America and Brasil), Web of Science/Web of Social Science, China National Knowledge Infrastructure (CNKI), CQ VIP (China)

Medical subject headings (MeSH) were used in addition to key words to maximize sensitivity and specificity of searches.

MeSH terms and keywords were PICO question-specific (see Annex 7 of the original guideline document for terms used; see the "Availability of Companion Documents" field).

Secondary reference searching was also conducted on all articles included in the review as well as in past systematic reviews and meta-analyses.

Conferences searched included:

- International AIDS Conference
- Conference on HIV Pathogenesis, Treatment, and Prevention
- Conference on Retroviruses and Opportunistic Infections

For the sex venue, internet-based, and social marketing interventions the following databases were also used: British HIV/AIDS Association, 2001-2008; Conference on Retroviruses and Opportunistic Infections (CROI), 1994-2008; European AIDS Society Conference, 2001 and 2003; International AIDS Society, International AIDS Conference (IAC), 1994-2004; International AIDS Society, Conference on HIV Pathogenesis, Treatment and Prevention (IAS), 2001-2005; US National HIV Prevention Conference, 1999, 2003, and 2005; as well as CROI and International AIDS Society web sites for abstracts presented at conferences subsequent to those listed above (CROI, 2009-2010; IAC, 2006-2010; IAS, 2007-2009).

Articles and citations were downloaded, organized, and reviewed.

Inclusion Criteria

To be included in the systematic review and Grading of Recommendations Assessment, Development and Evaluation (GRADE) processes, an article had to meet the following criteria:

- Published in a peer-reviewed journal, or presented as an abstract at a scientific conference only if additional information could be gleaned from the author.
- Include information that is pertinent to at least 1 PICO question of interest.

Screening Abstracts

Two independent reviewers screened the titles and abstracts of citations identified through the search strategy for potential eligibility. Full text articles were obtained for all selected abstracts; each article was reviewed by two independent reviewers to determine eligibility given the above inclusion criteria. Differences between the two reviewers were discussed and resolved through consensus.

## Number of Source Documents

Not stated

## Methods Used to Assess the Quality and Strength of the Evidence

Expert Consensus

Weighting According to a Rating Scheme (Scheme Given)

## Rating Scheme for the Strength of the Evidence

Levels of Assessment of the Evidence

| Grade | Definition |
|---|---|
| High | Further research is very unlikely to change confidence in the estimate of effect |
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| Low | Further research is very likely to have an estimate of effect and is likely to change the estimate |
| Very low | Any estimate of effect is very uncertain |

## Methods Used to Analyze the Evidence

Systematic Review with Evidence Tables

## Description of the Methods Used to Analyze the Evidence

Data Extraction and Management

Data were extracted by two reviewers using standardized data extraction spreadsheets. Differences in data extraction will be resolved through consensus. The following information was gathered from each included study:

- Study identification: author(s); type of citation; year of publication
- Study description: location, setting & target group; years (period of study); description of the intervention; comparison groups; study design; sample size; age range, gender; random or non-random allocation of participants; length of follow-up (all if applicable)
- Outcomes and results: outcome measures; effect sizes; confidence intervals; significance levels
- Other information: limitations; references for follow-up; secondary effects/adverse effects

The World Health Organization (WHO) uses the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach for the development and review of recommendations. The first step of the GRADE approach is to rate the quality of evidence for each PICO question by outcome. This step entails consideration of study limitations, inconsistency, indirectness, imprecision and other limitations. The quality of the evidence is then graded as high, moderate, low or very low. A standardized table, the GRADE evidence table, presents the quantitative summary of the evidence and the assessment of its quality.

The second step of the GRADE approach is to move from "evidence to recommendation" for each of the PICO questions. This includes consideration of the quality of evidence, the balance of benefits and harms, community values and preferences and resource use. These factors affect both the recommendation's direction (for or against) and its strength (strong or conditional). Decision tables summarize these factors.

## Methods Used to Formulate the Recommendations

Balance Sheets

Expert Consensus

## Description of Methods Used to Formulate the Recommendations

World Health Organization (WHO) Guideline Development Process

WHO uses the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach for the development and review of recommendations. The initial steps entail identifying key topics, formulating the Population, Intervention, Comparison and Outcomes (PICO) questions (see Annex 1 of the original guideline document for a list of the PICO questions; see the "Availability of Companion Documents" field), scoping the literature to identify whether evidence reviews exist or recent evidence can be obtained, developing a comprehensive search strategy and identifying and retrieving relevant evidence, including evidence concerning both benefits and harms.

Outcome frameworks are developed to ensure that outcomes are selected in a transparent and comprehensive manner and prior to reviewing the evidence. Each framework describes all possible pathways, starting with the intervention, going through the intermediate outcomes and leading to the important outcomes.

Viral Hepatitis Guideline Development Process

The WHO Department of Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome (HIV/AIDS) led the development of these guidelines with the oversight of the WHO Guideline Review Committee. In 2010 a scoping exercise was carried out to review the literature and identify key programmatic issues related to viral hepatitis transmission among people who inject drugs (PWID). A subsequent expert consultation with civil society representatives and the Cochrane Collaboration Drug and Alcohol Review Group was held in September 2010 to formulate the PICO questions. Three systematic reviews were later conducted to address these questions using the GRADE methodology. A series of semi-structured interviews with service providers and PWID was carried out in late 2011 to obtain their perspectives, values and preferences on the draft recommendations for prevention of viral hepatitis in PWID.

A technical consultation was held in Geneva, Switzerland, in February 2012 to reach consensus on the recommendations on prevention, surveillance and HIV management in patients with viral hepatitis-HIV co-infection.*

The expert panel included public health professionals, clinicians, academics, programme managers, implementers, civil society representatives and

a GRADE methodologist. Appropriate geographical and gender representation was considered. The three systematic reviews on prevention in PWID were presented and discussed. The multidisciplinary expert panel assessed the evidence, risks and benefits, and values and preferences for each recommendation. The expert panel determined the direction of the recommendations and strength of the evidence.

Consensus was reached for all decisions. By consensus, one of the original PICO questions, "Should motivational interviewing versus no motivational interviewing be used in people who inject drugs?", was dropped. The expert panel noted the general low quality of evidence and the need for further research in the area of hepatitis B virus (HBV) and hepatitis C virus (HCV) prevention among PWID. Consequently, the expert panel developed a series of research questions that should be addressed in the future.

*The process details for the surveillance and treatment components of the meeting are separate from the original guideline document and will be published elsewhere at a later date.

## Rating Scheme for the Strength of the Recommendations

Grading of Recommendations Assessment, Development and Evaluation (GRADE) Notation and Language

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## Cost Analysis

Vaccination

At a population level hepatitis B virus (HBV) vaccination has been demonstrated to be cost-effective, especially as the cost of the vaccine itself has declined in recent years. Cost-effectiveness is particularly apparent in countries with intermediate and high endemicity. The most cost-effective delivery of HBV vaccination is vaccinating without performing HBV antibody testing.

Type of Syringes

The panel judged the resources required to stock low dead-space syringes (LDSS) in existing needle and syringe program (NSPs) to be low, given the relatively similar costs associated with LDSS and high dead-space syringes (HDSS). The panel noted, nevertheless, the current limitations on the supply of LDSS, given that HDSS dominate the supply market and LDSS are manufactured in only a limited number of syringe

sizes.

Peer Interventions

The panel judged the value of peer interventions to depend on human resources. Peer-based interventions require the training of peers, particularly in settings where there are no trained peer workers. Nevertheless, the cost associated with training and employing peers is generally much less than the cost of training and employing health professionals. Given the limited data on effectiveness, however, the panel agreed that significant human resources should not be invested in this area.

### Method of Guideline Validation

External Peer Review

Internal Peer Review

### Description of Method of Guideline Validation

A draft version of the guidance was circulated among the expert panel members and external peer reviewers for feedback. The coordinators of the process incorporated comments from internal and external peer reviewers to finalize the guidelines.

## Evidence Supporting the Recommendations

### Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

## Benefits/Harms of Implementing the Guideline Recommendations

### Potential Benefits

Prevention of viral hepatitis transmission among people who inject drugs

### Potential Harms

Not stated

## Qualifying Statements

### Qualifying Statements

- The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement.
- The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by the World Health Organization in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.
- All reasonable precautions have been taken by the World Health Organization to verify the information contained in this publication.

# Implementation of the Guideline

## Description of Implementation Strategy

Adapting These Guidelines

These guidelines have been developed for a global audience. It is expected that regions and countries will adapt the recommendations to suit their own circumstances. These circumstances include the epidemiology of viral hepatitis in the country, social and cultural norms and economic factors. In order to achieve the desired impact of this guidance, these recommendations should be implemented at the national level. A national alliance composed of government, civil society, non-governmental organizations and donors is crucial to attain this objective.

This guidance is intended to be adapted to regional and local needs in line with national and sub-national strategies and inclusive of all partners. Regional and local requirements should be informed by epidemiological and needs assessments and take into account the existing programmatic response. Policy-makers should consider how the recommendations in this set of guidelines align with recommendations in other World Health Organization (WHO) guidelines. This guidance is not intended as a stand-alone document but rather one in the context of previous and future WHO guidance.

WHO and ministries of health, along with key stakeholders, should participate in country-level programme reviews to support adaptation and implementation of the guidelines*. Feedback from communities and other stakeholders will help to guide revision of the next edition of these guidelines.

*For a guide to adapting WHO HIV guidelines, see: Adapting WHO normative HIV guidelines for national programmes: essential principles and processes . Geneva, World Health Organization, July 2011.

Operational and Implementation Issues

It is recommended that this guidance be implemented in phases, consistent with the level of resources available. Consideration should be given to building awareness of this guidance among health-care workers and people who inject drugs (PWID). Specific issues regarding viral hepatitis among PWID that should be considered in the implementation of these guidelines in the local context include health systems, prevention services and community involvement.

*Health Systems*

Health systems should work to increase awareness of viral hepatitis among health-care workers. The approach should include, but not be limited to, decreasing stigma towards most-at-risk populations and increasing the willingness of health-care workers to provide services to them. Efforts to decrease stigma involve addressing service providers' beliefs about and attitudes towards these populations. Also, health systems should build the capacity of healthcare providers working with PWID to offer viral hepatitis and human immunodeficiency virus (HIV) prevention, testing, and diagnosis and treatment services.

*Prevention Services*

Prevention services should promote health and treatment literacy about viral hepatitis transmission and prevention and should offer hepatitis B virus (HBV) vaccination for PWID. In addition, prevention services should advocate and implement a comprehensive package of harm reduction interventions.

*Community Involvement*

PWID community groups should be involved in implementing the response to this guidance to ensure that it is meets community needs. It is important to consider the context in which injecting drug use occurs and in which services for PWID are delivered.

## Implementation Tools

Quick Reference Guides/Physician Guides

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

# Institute of Medicine (IOM) National Healthcare Quality Report Categories

## IOM Care Need

Living with Illness

Staying Healthy

## IOM Domain

Effectiveness

Patient-centeredness

# Identifying Information and Availability

## Bibliographic Source(s)

World Health Organization. Guidance on prevention of viral hepatitis B and C among people who inject drugs. Geneva (Switzerland): World Health Organization (WHO); 2012. 46 p. [142 references]

## Adaptation

Not applicable: The guideline was not adapted from another source.

## Date Released

2012

## Guideline Developer(s)

World Health Organization - International Agency

## Source(s) of Funding

The development of these guidelines received financial support from the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) through the Centers for Disease Control and Prevention (CDC).

## Guideline Committee

Guidelines Working Group

## Composition of Group That Authored the Guideline

*Guideline Authors*: Nick Walsh (independent consultant) and Annette Verster of the Department of HIV/AIDS, WHO Headquarters, with support from Michelle Rodolph and Elie Akl

A list of all contributors to the development of the guideline is available in the original guideline document.

## Financial Disclosures/Conflicts of Interest

Declaration of interest forms were collected from every member of each Guidelines Working Group. Eight potential conflicts of interest were declared. The World Health Organization (WHO) Secretariat assessed these declared conflicts of interest and determined that they were not sufficient to preclude these eight participants from participating in the development of the guidelines.

## Guideline Status

This is the current release of the guideline.

## Guideline Availability

Electronic copies: Available in Portable Document Format (PDF) from the World Health Organization Web site.

Print copies: Available from the WHO Press, World Health Organization, 20 Avenue Appia, 1211 Geneva 27, Switzerland; Phone: +41 22 791 3264; Fax: +41 22 791 4857; E-mail: bookorders@who.int.

## Availability of Companion Documents

The following are available:

- Policy brief. Guidance on prevention of viral hepatitis B and C among people who inject drugs. 4 p. 2012 Jul. Electronic copies: Available from the World Health Organization (WHO) Web site.
- Annexes: Guidance on prevention of viral hepatitis B and C among people who inject drugs. Electronic copies: Available from the WHO Web site.

Print copies: Available from the WHO Press, World Health Organization, 20 Avenue Appia, 1211 Geneva 27, Switzerland; Phone: +41 22 791 3264; Fax: +41 22 791 4857; E-mail: bookorders@who.int.

## Patient Resources

None available

## NGC Status

This NGC summary was completed by ECRI Institute on December 5, 2012. This summary was updated by ECRI Institute on June 2, 2016 following the U.S. Food and Drug Administration advisory on Opioid pain medicines.

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